



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/661,827 | 09/12/2003 | Andreas Hartlep | SCHWP0177USA | 7728 |

7590 09/03/2008
RENNER, OTTO, BOISSELLE & SKLAR, LLP
Nineteenth Floor
1621 Euclid Avenue
Cleveland, OH 44115-2191

| |
|----------|
| EXAMINER |
|----------|

CHAO, ELMER M

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3737

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/661,827 | Applicant(s) HARTLEP ET AL. | |
| | Examiner ELMER CHAO | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/28/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/05/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made of the amendment filed 5/28/2008.

Response to Arguments

2. Applicant's arguments with respect to **claim 1-16 and 18-22** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 3-12, 21, and 22** are rejected under 35 U.S.C. 102(b) as being anticipated by Kucharczyk et al. (U.S. 6,026,316).

Regarding **claims 1, 3-5, 7, 10-12, 21, and 22**, Kucharczyk et al. teach a method for planning the introduction of a fluid in a tissue, the method comprising: capturing via an imaging system functional anatomical data and/or structural anatomical data before infusion of a fluid into the tissue (Fig. 7, second box from the top); evaluating the captured functional and/or structural anatomical data with computer assistance and without the use of an infusion fluid (Fig. 7, three horizontal boxes third from the top); based on the evaluating step, identifying directional channels within the tissue and

Art Unit: 3737

determining infusion distribution information related to the identified directional channels, the identified directional channels and/or infusion distribution information being indicative of advantageous and/or non-advantageous infusion regions (Fig. 7, sixth box from the bottom); and presenting identified advantageous and/or non-advantageous infusion regions for viewing by a user (Fig. 7, sixth box from the bottom); and based on the advantageous and/or non-advantageous infusion regions, using medical navigation to introduce an infusion device at a selected point (Fig. 7, last box & three horizontal boxes third from the top).

Regarding **claim 6**, Kucharczyk et al. teach evaluating the functional and/or structural anatomical data over a period of time with respect to the distribution information (Fig. 7, third box from the top); and making adjustments in the distribution information, said adjustments being responsive to anatomical or structural conditions which have changed over the period of time (Fig. 7, last four boxes).

Regarding **claim 8**, Kucharczyk et al. teach ways of identifying isotropy and anisotropy of flow directions in the regions in the tissue (Fig. 7, sixth box from the bottom).

Regarding **claim 9**, Kucharczyk et al. teach calculating a distribution volume (col. 6, line 56 – col. 7, line 26).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3737

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk et al. Kucharczyk et al. teach the limitations as discussed above but fail to explicitly teach a program stored on a medium to carry out all of the steps. However, using a program to execute steps that would otherwise be performed manually is well-known in the art. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to have a program perform all of the steps in order to automate a manual process (see *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)).

8. **Claims 2, 13-15, 18, and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk et al., in view of Gillies et al. (U.S. 6,272,370).

Regarding **claim 2**, Kucharczyk et al. teach the limitations as discussed above but failed to explicitly teach the evaluating step including simulating the infusion at a plurality of regions in the tissue. However, in the same field of endeavor Gillies et al. teach simulating the infusion at a plurality of regions in the tissue (col. 16, line 28 - col. 17, line 21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to simulate the infusion at a plurality of regions in the tissue in

Art Unit: 3737

order to predict the response of the tissue to infusion before actually carrying out the infusion procedure (for motivation see col. 16, line 32-34).

Regarding **claims 13-15, 18, and 19**, Kucharczyk et al. teach all of the above limitations. Kucharczyk et al. does not explicitly teach the infusion at the selected point being planned using stereotactic planning and navigation. However, Gillies et al. teach the use of stereotactics in combination with magnetic resonance imaging in the planning and navigation for drug delivery (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Kucharczyk et al. to use Gillies et al.'s method to perform the infusion after the infusion site has been selected. Such a modification would produce a method of drug delivery that is more accurate and less damaging to other areas around the target area (col. 10, lines 1-9).

9. **Claims 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk et al., in view of Gillies et al., and further in view of Strommer et al. (U.S. 6,233,476 B1). Kucharczyk et al. and Gillies et al. teach all of the above limitations. Kucharczyk et al. and Gillies et al. do not explicitly teach the imaging device, processor, and the medical planning and navigation system being connected together. However, Strommer et al. teach a medical positioning system in which the processor, imager, and navigation system are all connected together (col. 4, lines 46-55). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Kucharczyk et al. and Gillies et al. such that the imaging device, the processor, and the medical planning and navigation system are connected to each other. Such a

Art Unit: 3737

modification would allow for the location of the catheter or infusion device to be located and superimposed on the image obtained from the imager (col. 4, lines 46-55).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

Art Unit: 3737

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art
Unit 3737

/E. C./
Examiner, Art Unit 3737
8/28/2008